37. (Amended) A method according to claim 32 wherein said mutation occurs in an activator protein-3 motif (AP-3) and/or a basic transcription element (BTE).

38. (Amended) A method according to claim 36 wherein said mutation occurs at any one of positions -475 or -147 of the transcription regulatory region adjacent to the sequence encoding CYP3A5, the sequence of which region is illustrated in Figure 7.

39. (Amended) A method according to claim 32 wherein the transcription regulatory region comprises the mutations $T_{-475}G$ and $A_{-147}G$.

REMARKS

The specification has been amended to incorporate the priority information for this Application. The claims have been amended solely for the purpose of removing multiple dependencies and aligning the claims to an acceptable claim format for U.S. examination. A substitute sequence listing has been provided along with a Computer Readable Form of the Sequence Listing. The undersigned hereby states that the Paper Copy and the Computer Readable Form are identical. No new matter has been added by these amendments. A version to show changes made accompanies this amendment. Favorable consideration of the remarks provided below is respectfully requested. Should the Examiner have any questions they are invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Myra H. McCormack
Attorney for Applicants
Reg. No. 36,602

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-6932
Dated: June 21, 2001

VERSION TO SHOW CHANGES MADE

IN THE SPECIFICATION

The claims have been amended as follows:

3. (Amended)A method according to claim 1 [or 2] comprising screening for said one or more variants in a recognition site for a transcription factor of said regulatory region.

4. (Amended) A method according to [any of] claim[s] 1 [to 3] comprising screening for said one or more variants in an activator protein-3 motif (AP-3) and/or basic transcription element (BTE).

5. (Amended) A method according to [any of] claim[s] 1 [to 4], comprising screening for said one or more variants at <u>at least one</u> [any one] of positions -475 or -147 of the transcription regulatory region of the sequence encoding CYP3A5 the sequence of which region is illustrated in Figure 7.

7. (Amended) A method according to [any of] claim[s] 1 [to 5] wherein said DNA is amplified using oligonucleotide molecules which are capable of hybridising selectively to the wild type or variant sequences respectively such that generation of amplified DNA from said respective molecules will indicate whether said wild type or said variant is present.

10. (Amended) A method according to claim 8 [or 9] wherein said molecule introduces a restriction site in a region corresponding to an activator protein-3

motif (AP-3) and/or a basic transcription element (BTE).

13. (Amended) A method according to claim 11 [or 12] wherein said oligonucleotide molecule comprises the sequence designated 3A5R1 illustrated in Figure 6.

16. (Amended) A method according to claim 14 [or 15] wherein said molecule comprises the sequence designated 3A5F2 illustrated in Figure 6.

19. (Amended) A molecule according to claim 17 [or 18] which is capable of hybridising to an activator protein-3 motif (AP-3) or a basic transcription element.

20. (Amended) A molecule according to [any of] claim[s] 17 [to 19] which is capable of hybridising to a region comprising a polymorphic variant at <u>at least one</u> [any] of positions -475 or -147 of the transcription regulatory region of the sequence encoding CYP3A5 illustrated in Figure 7.

21. (Amended) A molecule according to any of claim[s] 17 [to 20] which comprises any of the sequences designated 3A5F1, 3A5F2 or 3A5R1 illustrated in Figure 6.

22. (Amended) A kit for performing the method of [any of] claim[s] 1 [to 7] comprising an oligonucleotide molecule <u>of at least 10 contiguous nucleotides capable of amplifying a DNA sequence to detect a wild type or polymorphic variant in a transcription regulatory region of a sequence encoding</u>

cytochrome CYP3A5 said associated with a high or low drug metabolising phenotype respectively, which molecule is capable of hybridising to a region incorporating either a polymorphic variant or wild type nucleotide in said region, such that amplification of said wild type and polymorphic variants will proceed from said molecule only when an oligonucleotide includes a sequence corresponding to either said wild type or polymorphic variant characteristic of a high drug metabolising phenotype [according to any of claims 17 to 21] and means for contacting said molecule and said transcription regulatory region of the sequence encoding CYP3A5.

28. (Amended) A method according to claim 26 [or 27] comprising screening for said variant in an activator protein-3 motif (AP-3) and/or a basic transcription element (BTE) of said transcription regulatory region.

29. (Amended) A method according to [any of] claim[s] 26 [to 28], comprising screening for said variant at at least one [any one] of position -475 or -147 of the transcription regulatory region of the sequence encoding CYP3A5 the sequence of which region is illustrated in Figure 7.

30. (Amended) A method according to [any of] claim[s] 26 [to 29] comprising screening for both variants at position -475 or -147.

31. (Amended) A method according to [any of] claim[s] 26 [to 30] comprising screening for the

presence or absence of variants $T_{-475}G$ and $A_{-147}G$ in said transcriptional regulatory control region.